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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,596	04/13/2001	Kyoichi A. Watanabe	PHARM1	4260
7590	05/24/2005			
Madeline I. Johnson King & Spalding 191 Peachtree Street Atlanta, GA 30303-1763			EXAMINER OWENS JR, HOWARD V	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/834,596		WATANABE ET AL.	
	Examiner		Art Unit	
	Howard V. Owens		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7,9,11,19,21,26,27,41-56 and 65-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 26,27,45-48,53-56 and 69-72 is/are allowed.
- 6) ☒ Claim(s) 5-7,9-11,19,21,41-44,49-52,65-68 and 73-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/02/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

The following is in response to the amendment filed 3/02/05:

An action on the merits of claims 5-7,9,11,19,21,26,27,41-56 and 65-80 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections to the specification

The specification sets forth the variable "R' " to define a D and L aminoacyl group (p. 7). However, there is no definition for this R' variable, nor are there any examples demonstrating what constitutes the R' variable.

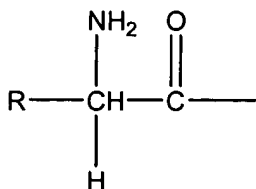
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7, 9-11, 19, and 21, 41-44, 49-52, 65-68 and 73-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 9, 19 and 21 contain the D and L aminoacyl group variable :



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to describe "R" for formulae I – IV. The claim does not provide any definition as to what constitutes "R" in this moiety; moreover, the specification does not provide any evidence as to what the R variable for this moiety should constitute. Dependent claims 6, 7, 10, 11, 41-44, 49-52, 65-68 and 73-76 are also rejected as they fail to remedy the deficiency of the parent claim(s).

Claim Rejections - 35 USC § 102

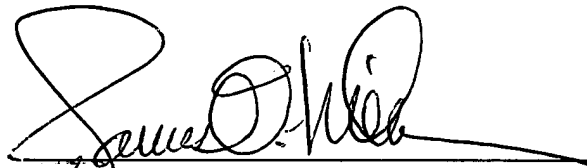
The rejection of claims 1-3, 17, 34 and 58 under 35 U.S.C. § 102(b) as being anticipated by Gosselin et al., U.S. 6,395,716 is withdrawn in view of applicant's amendment to the claims.

Allowable Subject Matter

Claims 26, 27, 45-48, 53-56 and 69-72 appear to contain subject matter allowable over the prior art of record, specifically, the 2' and 3' substituted nucleotide compounds for the treatment of HCV and process for preparing the compounds thereof have not been set forth in the prior art of record.

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Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.